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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,129	08/22/2003	Todd Bucciarelli	MBHB04-101-C	8860

7590 05/31/2006

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,129

Applicant(s)

BUCCIARELLI ET AL.

Examiner

Michail A. Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 and 63 is/are pending in the application.
4a) Of the above claim(s) 1-30 and 43-56 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 31-42 and 57-60 and 63 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 04/26/06 is acknowledged.

Claims 1-60 and 63 are pending.

Claims 1-30 and 43-56 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 31-42 and 57-60 and 63, drawn to an expression vector comprising a minimal promoter comprising TATA sequence and two phase tetracycline operators downstream from TATA sequence and two phased tetracycline operators downstream from TATA sequence are under consideration in the instant application.

In view of the amendment, filed 04/26/06 the following rejections remain:

2. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 31-42 and 57-60 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 31-42 and 57-62 are indefinite and ambiguous in the recitation of "two phased tetracycline operators". The metes and bounds of the phrase "two phased tetracycline operators" is unclear. It might mean one operator working in two-phase mode or two operators?

5. Claim 32 and 34 are indefinite and ambiguous in the recitation of "two phases tetracycline operators downstream from the TATA sequence are 21 basepairs downstream from the TATA sequence". If the claimed expression vector comprises **two** tetracycline operators that both located downstream from the TATA sequence, then it is unclear how each of the two operators can be located 21 basepairs downstream from the TATA sequence ?

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6. Claim 33 and 34 are indefinite and ambiguous in the recitation of “ two phases tetracycline operators upstream from the TATA sequence are 11 basepairs upstream from the TATA sequence”. If the claimed expression vector comprises **two** tetracycline operators that both located upstream from the TATA sequence, then it is unclear how each of the two operators can be located 11 basepairs upstream from the TATA sequence ?

7. Claim 42 is indefinite and ambiguous in the recitation of “ wherein the vector encodes more than one cyclin-dependent kinase inhibitor”. The base claim 39 recites a vector comprising **a gene** that encodes **a cyclin dependent kinase inhibitor**. In other words, the claimed vector encoded only one cyclin-dependent kinase inhibitor. It is unclear how said vector, comprising only one specific gene can encode more than one cyclin-dependent kinase inhibitors?

Applicant's arguments, filed 04/26/06 have been fully considered, but have not been found convincing.

Applicant asserts that : the term “phase” would be understood by one having ordinary skill in the art that the operator sequences were positioned in any way that their effect on gene expression complemented rather than opposed each other ; (ii) one skill in the art would understand that two phase tetracycline promoters are intended to be positioned at the site that is 21bp downstream or 11 bp upstream from TATA box. (iii) claim 42 has been amended and thus rejection should be withdrawn in light of the amendment.

Contrary to Applicant's assertion it is the Examiner position that the term “two phased tetracycline operators “ is indefinite and ambiguous. It might means one operator working in two-phase mode or two operators. It is suggested that claims be amended to recite for example “ an expression vector comprising an inducible transcription regulation element comprising at least two tetracycline operator elements, wherein the tetracycline operator elements are arranged such that a first and a second phased tetracycline operator are downstream from the TATA sequence and the third and fourth phased tetracycline operator are upstream of the TATA sequence” for clarity and consistence with the disclose of the specification.

With regards to amended claim 42.

The issue raised by the Examiner was that the base claim 39 recites a vector comprising **a gene** that encodes **only one** cyclin dependent kinase inhibitor. It is unclear how a vector, comprising only a **gene** that encode only one cyclin dependent kinase inhibitor can encode **more than one** cyclin-dependent kinase inhibitors?

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8 . Claims 57-60 and 63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“ The expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Cy motifs, wherein the Cy motifs encode a peptide having an amino acid sequence identified by SEQ ID Nos:3,4,5,6,7,8,9,10,11,12,or 13 ” claimed in claims 57-60 and 63 represent(s) a departure from the specification and the claims as originally filed. The specification and the claims as originally filed only support “The expression vector of claim 31, wherein the expression vector encodes cyclin-dependent kinase inhibitors selected from the group recited in claims 41 and 42.

Applicant's arguments, filed 04/26/06 have been fully considered, but have not been found convincing.

Applicant asserts that disclosure of the Specification on pages 19 –20 and in Table I fully supports claims 57-60 and 63.

Contrary to Applicants assertion, it is noted that specification on pages 19 and 20 only generly disclosed that peptides that may be used include Cy regions peptide. Table I only disclosed several known peptides that have Cy motif in their sequences.

It is the Examiner position that “ The expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Cy motifs, wherein the Cy motifs encode a peptide having an amino acid sequence identified by SEQ ID Nos:3,4,5,6,7,8,9,10,11,12,or 13 ” claimed in claims 57-60 and 63 represent(s) a departure from the specification and the claims as originally filed.

The following new grounds of rejection is necessitated by the amendment filed 04/26/06

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 59, 60 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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11. Claim 59 is indefinite and ambiguous in the recitation of “wherein the Cy motifs encode a peptide having an amino acid sequences identified by SEQ ID Nos:3,4,5,6,7,8,9,10,11,12,or 13. The Specification on page 19, Table I disclosed that SEQ ID Nos: 3, 4,5, 6,7,8,9,10,11,12,or 13 **are Cy motifs themselves** that are found in many proteins involved in cell cycle dynamics. It is unclear how Cy motifs **can encode a peptide** having an amino acid sequences identified by SEQ ID Nos:3,4,5,6,7,8,9,10,11,12,or 13 ?

12. Claim 60 is indefinite and ambiguous in the recitation of “ The method of clams 57 or 58”. There is insufficient antecedent basis for this limitation in the claims, since base Claims 57 or 58 does not recite “a method.

13. Claim 63 is indefinite and ambiguous in the recitation of “ The method of clams 59” There is insufficient antecedent basis for this limitation in the claims, since base Claims 59 does not recite “a method”.

14. No claim is allowed

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 26, 2006


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